

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

**In re: Santa Fe Natural Tobacco Company
Marketing, Sales Practices, and Products
Liability Litigation**

No. 1:16-md-2695-JB-LF

This Submission Relates to All Actions.

**SANTA FE NATURAL TOBACCO COMPANY’S SUPPLEMENTAL BRIEF
IN SUPPORT OF MOTION TO DISMISS RESPONDING TO THE COURT’S
QUESTION REGARDING STATUS OF AGREEMENT WITH FDA REGARDING
NAS PRODUCT LABELING AND ADVERTISING**

In response to the Court’s question at the November 21, 2017, conference regarding the status of the January 2017 agreement (the “Agreement”) between Santa Fe Natural Tobacco Company (hereinafter “Santa Fe”) and the United States Food & Drug Administration (“FDA”) regarding Natural American Spirit (“NAS”) cigarettes, Santa Fe states as follows:

1. On January 23, 2017, Santa Fe and FDA reached the Agreement by which Santa Fe will remove the phrases “Additive Free” and “Natural” from all NAS cigarette product labels, labeling, advertising, and promotional materials, provided that Santa Fe may retain use of the term “Natural” in the NAS brand name and trademarks. The Agreement permits Santa Fe to use the statement “Tobacco Ingredients: Tobacco and Water” and “Tobacco Filler Ingredients: Tobacco and Water” on NAS labeling, advertising, and promotional materials. The Agreement further provides that if such statements are used, FDA will not object to use of the following disclaimer: “Natural American Spirit cigarettes are not safer than other cigarettes.”

2. The Agreement recognizes that any agreed-upon change in NAS labeling, packaging, advertising, and promotional material needed to account for the 2000 Consent Decree between Santa Fe and the Federal Trade Commission (“FTC”) regarding advertising for NAS. The 2000 FTC Consent Order, among other things, required Santa Fe to include the following

disclosure in NAS cigarette advertising: “No additives in our tobacco does **NOT** mean a safer cigarette.” Santa Fe was required to initiate discussions with the FTC within 30 days of the Agreement, and to work diligently with the FTC and FDA to resolve this issue.

3. Both Santa Fe and FDA understood that neither had any control over the FTC, and that it could be several months or longer before the FTC would conclude its administrative process. FDA also recognized that revisions to packaging, product labeling, promotional materials, and advertising require substantial lead time to develop, finalize, print, and implement. With those factors in mind, the Agreement requires that Santa Fe complete the mandated labeling changes—specifically including removal of the phrases “Additive Free” and “Natural” from all NAS cigarette product labels, labeling, advertising, and promotional materials—within seven months from the date Santa Fe receives in writing the FTC’s position on whether the FTC would object to the use of the revised disclosure provided for in the Agreement, *i.e.*, “Natural American Spirit cigarettes are not safer than other cigarettes.”

4. On January 31, 2017, Santa Fe, by and through its outside counsel, initiated the dialogue with the FTC as required by the Agreement. On May 9, 2017, the FTC’s Division of Advertising Practices issued its written Informal Staff Guidance indicating, in effect, that it had no objection to the use of the modified disclosure statement. That Informal Staff Guidance triggered the seven-month timeline for implementation of the revisions to NAS packaging, product labeling, promotional material, and advertising required by the Agreement.

5. Following the FTC review, and as required by the Agreement, on June 2, 2017, Santa Fe provided FDA with exemplars of the proposed revised NAS packaging, product labeling, promotional materials, and advertising. On June 29, 2017, FDA notified Santa Fe that it deemed the exemplars to comply with the changes required by the Agreement.

6. While the seven-month transition period does not close until December 9, 2017, Santa Fe is no longer utilizing the phrases “Additive Free” and “Natural” in the NAS cigarette product labels, labeling, advertising, and promotional materials that it is producing (except for use of the term “Natural” in the NAS brand name and trademark, as the Agreement expressly permits), and Santa Fe is in compliance with the Agreement.

7. Paragraph 2 of the Agreement addresses directly the issue raised by Plaintiffs’ Counsel during argument about the continued availability of NAS cigarettes with “additive free” and “natural” claims. Paragraph 2 states in pertinent part:

Santa Fe need not, however, remove or recall products or product labels, labeling, advertising, or promotional materials utilizing the terms “additive free” or “natural” that were introduced into the market (e.g., through distribution to wholesalers, distributors, retailers, or consumers) prior to the seven (7) month deadline.

Dated: November 29, 2017

Respectfully submitted,

/s/ David M. Monde

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CERTIFICATE OF SERVICE

I hereby certify that on November 29, 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF System, which will send a notice of electronic filing to all counsel or parties of record.

Dated: November 29, 2017

Respectfully submitted,

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